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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,849	07/22/2005	Werner Wessling	R00957US (#90568)	1323
7590 10/05/2009 D Peter Hochberg Company The Baker Building 6th Floor 1940 East 6th Street Cleveland, OH 44114-2294				
EXAMINER				
PALENIK, JEFFREY T				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
10/05/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/517,849

**Applicant(s)**

WESSLING, WERNER

**Examiner**

Jeffrey T. Palenik

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4-35 is/are pending in the application.
- 4a) Of the above claim(s) 9-16, 20, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 17-19, 21, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

**STATUS OF APPLICATION**

Receipt is acknowledged of Applicant's After Final Amendment and Remarks filed on 18 September 2009, in response to the FINAL rejection mailed on 18 June 2009, in the matter of Application N° 10/517,849. Applicants' amendments and remarks are entered on the record. The Examiner further acknowledges the following:

Applicant has requested reconsideration of the finality of the last Office action on the grounds that the Examiner mailed an Advisory Action which indicated that the proposed amendments to claims 1 and 34, if entered, would be sufficient to overcome the present rejections of record. Applicant, in view of this, submitted a Request for Continued Examination and the claims were entered. However, upon re-consideration of the art of record, the Examiner discovered that said art still read on the amended claims, namely claims 1 and 34. Per MPEP §706.07(b), making an Action Final on the first action is not proper where claims have been denied entry on the grounds of (A) new issues having been raised, or (B) new matter issues.

**Thus, in view of the forgoing comments, Applicant's request for the withdrawal of finality of the previous action is persuasive.**

Regarding Applicant's presently entered claims:

Claim 17 alone has been amended. It now depends from claim 1, rather than improperly depending from claim 3.

No claims are newly cancelled or added.

No new matter has been added.

Claims 1, 4-8, 17-19, 21, 34 and 35 continue to represent all claims currently under consideration.

#### **INFORMATION DISCLOSURE STATEMENT**

No new Information Disclosure Statements (IDS) have been filed for consideration.

#### **MAINTAINED REJECTIONS**

The following rejection is maintained from the previous Office Correspondence dated 18 June 2009:

#### **CLAIM REJECTIONS - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-8, 17-19, 21, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whittle et al. (US Pre-Grant Publication No. 2002/0136752).

The instant amended claims are drawn to a film-shaped mucoadhesive composition containing a cannabis extract comprising tetra-hydrocannabinol (THC) and at least one further cannabinoid, said film having a thickness of 0.5 mm or less (claim 1). The polymer administration form is recited as comprising a polymer matrix and representing a percent by weight of the composition (claims 2, 3 and 17). The administration form is recited as comprising a percentage of cannabis extract (claims 4 and 18). The administration form is recited as further comprising additional flavoring and odorous compounds (claims 5 and 19). The thickness of the overall composition is further limited (claims 6 and 21). The administration form is recited as further comprising at least one inactive ingredient (claim 7) and as having multiple layers wherein at least one layer contains an active agent (claim 8). New claim 34, as discussed above, does not further limit claim 1 since, cannabis oils, absent a clearer definition, are interpreted in the same scope as cannabis extracts. Claim 35 recites species limitations to cannabinoids.

Whittle et al. teach a film-shaped, pharmaceutical formulation for administration to a mucosal surface, wherein the formulation comprises at least one lipophilic medicament and a matrix which comprises at least one emulsifying agent and a sweetening or flavoring agent (claim 1 and Examples 9). Example 9 expressly teaches a melted mass (i.e. matrix) formulation which serves as a reservoir for two cannabis active ingredients: tetrahydrocannabinol (THC) and cannabidiol (CBD). The formulation expressly teaches the presence of a cannabis extract (e.g. THC) and a cannabinoid compound present, each in the amounts of 5 parts per 90 parts (e.g. about 5.5% by weight). Absent any evidence to the contrary, the units “parts” is interpreted by

the Examiner as teaching “percent by weight”. This expressly teaches the instantly claimed limitations of claims 1, 2, 4, 18, 34 and 35. The composition of Example 9 further teaches the instantly claimed a water-soluble polymer limitation of claims 3 and 17 whereby it contains gum Acacia (e.g. a water-soluble natural gum) in the amount of 20 parts per parts (e.g. about 22% by weight). The Example also teaches the instantly claimed odorous substances limitation of claims 5, 7 and 19 whereby the taught composition contains vanillin. The limitations of claim 7 are also expressly taught by both claim 1 and Example 9, which respectively teach the inclusion of an emulsifying agent in the form of glyceryl monoleate. Lastly, Example 9 and Figures 1-4 teach that the composition must not only be able to fit comfortably inside oral cavity, but also conform to a thickness requirement. Example 9 expressly teaches a preferred thickness of 2.5 mm, achieved by rolling out the hot-melted mass into a sheet. Example 11 expressly teaches the limitations of the instant claims 1, 2, 4, 8, 18, 34 and 35, whereby the mucoadhesive composition comprises both a cannabis extract and a cannabinoid, again THC and CBD, and within the claimed percentages. The limitations of claim 8 are expressly taught in Example 11, which teaches a two-layered composition the first layer of which comprises THC in the amount of 15 parts per about 133 parts (e.g. about 7.5% by weight) and the second layer of which comprises CBD in the amount of 20 parts per about 165 parts (e.g. about 12.1% by weight). The overall composition thus comprises 15 parts per about 298 parts of THC (e.g. about 2% by weight). The overall composition further comprises 15 parts Acacia gum and 100 parts glycolgelatin per 298 parts (e.g. about 38.6% by weight) as well as glyceryl monoleate as the emulsifying agent. Example 10, which teaches no specific formulations, serves to further elaborate on the final

forms which are applicable to the different Examples, citing specifically that the melted molds may be molded or cast into films.

Though Whittle expressly teaches nearly every aspect of the instantly invention, the teachings do not expressly teach the overall administration form as conforming to the instantly claimed thickness limitations.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prepare the instantly claimed single- or multi-layered, cannabis extract/cannabinoid mucoadhesive administration form, as taught and suggested by Whittle, modify the thickness of the cast film form, and produce the instantly claimed invention.

One of ordinary skill in the art would have been highly motivated to do this because Whittle expressly teaches each of the aforementioned aspects of the instantly claimed invention with the exception of conforming said article to the claimed dimensions. Furthermore, as discussed above, in view of Figures 1-4 and Examples 9-10 of the invention practiced by Whittle, it would have been *prima facie* obvious to a person of ordinary skill in the art to optimize the thickness parameter of the administration forms (see MPEP §2144.04 (IV)(B.)) for any number of reasons related to the efficacy or aesthetic aspects of the invention (i.e. to be able to accommodate the variety different oral or buccal locations to which the form will be applied). Thus, absent some demonstration of unexpected results or criticality from the claimed parameters, optimization of any of the thickness parameter would have been obvious at the time of Applicant's invention.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

#### **RESPONSE TO ARGUMENTS (PREVIOUS ACTION)**

Applicant's arguments with regard to the rejection of claims 1, 4-8, 17-19, 21, 34 and 35 under 35 USC 103(a) as being unpatentable over the teachings of Whittle et al. have been fully considered but they are not persuasive.

Applicant has amended claims 1 and 34 removing gum acacia from the polymer matrix limitation, thereby alleging that Whittle now fails to teach every feature of the present claims since the polymer matrix of the mucoadhesive administration forms as presently claimed are prepared from polymers which are clearly different from the polymers taught by Whittle.

In response, the Examiner respectfully disagrees and submits that in reconsideration of the Whittle reference, it was discovered that Applicant's claims continue to recite hydroxypropyl cellulose, an emulsifying, stabilizing and viscosity modifying polymer, which is expressly taught in Table 2 of Whittle. It is thus considered by the Examiner, in view of the Table and the Examples that the ordinarily skilled artisan would have been motivated to substitute in hydroxypropyl cellulose for acacia as they are taught as being functionally equivalent viscosity modifying polymers. That the polymers listed in the Table are used in gels formed by combining substances of opposite electrical charges, as Applicant points out, is irrelevant given that



electrical charge of the polymers is not a limitation which was considered in the rejected claims.

For these reasons, Applicant's arguments are found unpersuasive. Said rejection is therefore **maintained**.

#### **RESPONSE TO PRESENT ARGUMENTS**

Applicant's new presented remarks with regard to the maintained rejection of claims 1, 4-8, 17-19, 21, 34 and 35 under 35 USC 103(a) as being unpatentable over the teachings of Whittle et al. have been fully considered, but are not persuasive.

Applicant states that the ordinarily skilled artisan would not be motivated to substitute acacia with hydroxypropyl cellulose because acacia is a negatively charged coacervating agent which reacts with positively charged gels such as gelatin. Further, the skilled person would not be motivated to replace a charged polymer with a neutral polymer since the difference in surface charge would be expected to result in differing physio-chemical properties.

In response, the Examiner concedes the rejection based on the forgoing argument. However, the Examiner respectfully continues to disagree with Applicant on the point that Whittle does not teach and/or suggest every limitation of the instant claims. The Examiner submits that Applicant's base claims 1 and 34, as amended and entered, continue to recite that the polymer matrix contains (e.g. "comprises" per MPEP §2111.03) "at least one polymer being water-soluble or swellable in an aqueous medium, said at least one polymer is selected from the group consisting of ... hydroxypropyl cellulose, ... propyl cellulose, [and] ... alginates". Paragraph [0062] of Whittle expressly teaches that the agents described in Table 2 can be used to produce emulsification, mucoadhesion and an increase in viscosity and that "[m]any of the

agents can be used to alone or in combination to fulfill the role of primary or secondary emulsifier". This is interpreted as an express teaching, if not suggestion, that the polymers of Table 2 may be combined to form a polymer matrix such as that which is instantly claimed. Polymers which are expressly taught by Table 2, which continue to read on the instant base claims include hydroxypropyl cellulose as well as propylene glycol alginate; the latter being interpreted by the Examiner as a species to Applicant's instantly claimed genera of "propyl cellulose" and "alginates" polymers. It is further interpreted that the presence of acacia in the compositions of Whittle is irrelevant, particularly in view of the teaching that multiple agents may be concurrently employed and since the instant claims continue to recite "comprising" language where it concerns the polymer matrix constituents.

For these reasons, Applicant's arguments remain unpersuasive. Said rejection is therefore **maintained**.

All claims under consideration remain rejected; no claims are allowed.

#### **CONCLUSION**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### **CORRESPONDENCE**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615